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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,913	03/22/2004	Ashley J. Birkett	91645	2511
24628	7590	02/23/2007		
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			EXAMINER PENG, BO	
			ART UNIT 1648	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceedings.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,913	BIRKETT, ASHLEY J.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-109 and 116-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-109 and 116-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/06; 11/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2006 has been entered.
2. This Office Action is in response to the amendment filed September 21, 2006. Claims 101-109 and 116-118 are pending, and are under consideration in this Office action.

Information Disclosure Statement

3. Applicant's IDS form 1449 submitted on September 21 and November 22, 2006 has been considered by the examiner. The initialed and dated copies of IDS form 1449 are attached to the instant Office action.

35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of Claim 116 under 35 USC § 112, second paragraph is **withdrawn** in view of the amendment to the claim.

35 USC § 112, first paragraph

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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The rejection of Claims 101-109 and 116-118 under - 35 USC § 112, first paragraph, for lacking enablement, **is withdrawn** in view of the amendment to the claims.

35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The rejection of Claims 102, 106, 107 and 117 under 35 U.S.C. 102(b), as being anticipated by Zlotnick, **is withdrawn** in view of the amendment to the claims.

35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. The rejection of Claims 101-109 and 116-118 under 35 U.S.C. 103(a), as being obvious over Pumpens et al. (1995) in view of Zlotnick, is **maintained** for the reasons of record.

12. Applicant argues again that Pumpens' statement that foreign insertions exert a stabilizing effect on chimeric HBcΔ "leads away from the present invention whose active agent gains stabilization from an added C-terminal cysteine" (Remarks paragraph 1, p. 17).

13. In response, first, a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). Here in contrast to applicant's assertion of teaching away by Pumpens, the reference indicate a successful HBcΔ chimera; there is neither discouragement nor skepticism in the prior art for HBcΔ chimers. Secondly, as discussed in this and previous office actions, the feature of "the present invention whose active agent gains stabilization from an added C-terminal cysteine" is taught and suggested by Zlotnick. Therefore, the combine teaching of cited reference of Pumpens and Zlotnick does not constitute teaching away from the alleged invention.

14. Applicant also argues that Ulrich, as ordinary skill in the art, who stated that the stability problem of HBc was not solved, did not suggest that the desired stability could be achieved by combining teachings of Pumpens and Zlotnick or Zhou, whose disclosure about the effect of Cys on the stability of HBcΔ particles is substantially similar to Zlotnick's teaching, but rather maintained that the problem had yet to be solved (Remarks, p. 18-20).

15. Applicant's argument is not relevant. Even though Ulrich did not combine teachings of both Pumpens and Zlotnick, the knowledge of Pumpens and Zlotnick are still suggestive to those

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of ordinary skill in the art. In the instant claims, specifically, all basic structural feature limitations are taught or suggested by Pumpens and Zlotnick. Applicant has not explicitly pointed out which specific structures of the alleged HBc chimer are different from the prior art, and how they result in the alleged stability of the HBc chimer. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

16. The following are new rejections:

Claim Rejections - 35 USC § 112, first paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 101-109 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection affects all dependent claims.

19. Please note that the newly amended scope of "... and said particles being more stable on storage at 1 mg/mL using 50 mM NaPO₄, pH 6.8 than are particles formed from an otherwise identical HBc chimer molecule that lacks said C-terminal cysteine residue or in which a C-terminal cysteine residue present in the chimer molecule is replaced by another residue" in

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Claims 116-118 is NEW MATTER.

20. A survey of the specification failed to find support for that said recombinant chimeric HBc being “more stable on storage at 1 mg/mL using 50 mM NaPO₄, pH 6.8 than are particles formed from an otherwise identical HBc chimera molecule that lacks said C-terminal cysteine residue or in which a C-terminal cysteine residue present in the chimera molecule is replaced by another residue”.

21. Please also note that said chimera molecules “containing no more than about 5 percent conservatively substituted amino acid residues in the HBc sequence” in Claims 116-118 is NEW MATTER. A survey of the specification failed to find support for “containing no more than about 5 percent conservatively substituted amino acid residues in the HBc sequence”

Removal of all new matter is required. *In re Russsmussen* 210 USPQ 325.

Conclusion

22. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
2/16/07



**BRUCE R. CAMPELL, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**